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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/925,140	08/08/2001	Preeti Lal	PF-0512-1 DIV	3400

27904 7590 05/21/2003

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EXAMINER

HELMS, LARRY RONALD

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 05/21/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/925,140

Applicant(s)

LAL ET AL.

Examiner

Larry R. Helms

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 13-18, 27 and 28 is/are pending in the application.
- 4a) Of the above claim(s) 1, 2, 8, 10, 13-18, 27 and 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-7, 9 and 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. Claims 3 and 9 have been amended.
Claim 12 has been cancelled.
2. Claims 1-2, 8, 10, 13-18, 27-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions. Applicant timely traversed the restriction (election) requirement in Paper No. 6.
3. Claims 3-7, 9, 11 are under examination.
4. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action.
5. The following Office Action contains some NEW GROUNDS of rejection.

Rejections Withdrawn

6. The rejection of claims 3, 6, 7, 9 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendments to the claims.

Response to Arguments

7. The rejection of claims 3-7, and 9 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is maintained.

The response filed 3/18/03 has been carefully considered and is partially persuasive with respect to immunogenic fragments that generate an antibody that binds SEQ ID NO:1, however, the rest of the response has been carefully considered and is deemed not to be persuasive. The response states that claims 3 and 9 have been amended to recite biologically active fragment has "serine hydratase" activity. In response to this the polypeptide of SEQ ID NO:1 is taught to have serine dehydratase activity not "serine hydratase" activity. As such one skill in the art would not know how to determine the activity of a biologically active fragment of SEQ ID NO:1 which is claimed to have serine hydratase activity and the specification teaches an assay for serine dehydratase activity. In addition the response states that the claims are directed to polynucleotides not polypeptides and variants of 90% may be useful even if they lack serine dehydratase activity and the variants may be associated with disease states (see page 7 of response). In response to this argument, the claim is directed to a polynucleotide but the polynucleotide has to encode a polypeptide that is 90% identical to SEQ ID NO:1. Again, while one can screen for enzymatic activity the claims encompass variants that are 90% identical that do not have any function (see claim 3(b) for example) and as such one would not know how to use such polynucleotides.

Thus, undue experimentation would be required to use the instantly claimed polypeptides.

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8. The rejection of claims 3, 6-7, 9, 11 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained.

The response filed 3/18/03 has been carefully considered and is partially persuasive with respect to immunogenic fragments that generate an antibody that binds SEQ ID NO:1, however, the rest of the response has been carefully considered and is deemed not to be persuasive. The response states that one can select biologically active fragments of SDHH that have serine dehydratase activity using methods in Example X on page 50 (see page 9 of response). In response to this argument, the claims recite serine hydratase activity not serine dehydratase activity and as such one skill in the art would not know how to test the polypeptides for activity.

The response further states that the specification provides adequate written description of variants of SEQ ID NO:2 and one skill in the art would recognize naturally occurring variants and one could perform hybridization and/or PCR and one only need to screen a cDNA library to identify that which already exists in nature (see pages 10-12). In response to this argument, the rejection is based on written description and as such being able to screen a cDNA library is not on subject as this is not an enablement rejection. As stated before, the general knowledge in the art concerning variants does not provide any indication of how the structure of one variant is representative of unknown variants. Reiger et al. (Glossary of Genetics and Cytogenetics, Classical and Molecular, 4th Ed., Springer-Verlay, Berlin, 1976) clearly define alleles as one of two or

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more alternative forms of a gene occupying the same locus on a particular chromosome... and differing from other alleles of that locus at one or more mutational sites (page 17). Thus, the structure of naturally occurring sequences are not defined. With the exception of SEQ ID NO:1 the skilled artisan cannot envision the detailed structure of the encompassed polypeptides and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation.

The response further states that the present claims specifically define the claimed genus through the recitation of chemical structure and the subject matter of the present claims is defined in terms of chemical structure of the polynucleotide sequence of SEQ ID NO:2 or the amino acid sequence of SEQ ID NO:1 (see pages 13-15 of response). In response to this argument, although SEQ ID NO:1 and 2 are defined structural features, naturally occurring sequences at least 90% identical are not because these structures are not defined. The response further states that the genus is not highly variant and argues Brenner et al for support and the response states that in according to Brenner et al naturally occurring molecules may exist which could be characterized as serine dehydratases and which have as little as 30% identity over at least 150 residues of SEQ ID NO:1 (see page 15-16 of response). In response to this argument, the claim does not require a function and in addition, while there may be naturally occurring variants, the specification does not describe any variants of SEQ ID NO:1 or 2 or where in the sequence variants would exist and as such, one of skill in the

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art would not understand that the applicant had possession of the claimed invention at the time the instant application was filed.

The following are some NEW GROUNDS of rejections

Claim Rejections - 35 USC § 112

9. Claims 3-7, 9, 11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 3 and 9 have been amended to recite "has serine hydratase activity". The response filed 3/18/03 did not state where support can be found in the specification. The specification has support for serine dehydratase activity (see page 50) but the examiner was unable to find serine hydratase activity. Applicant is required to provide specific support for the claimed limitation in the specification as originally filed or remove it from the claims.

Conclusions

10. No Claims are allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37

CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 6:30 am to 4:00 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

13. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the

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Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242.

Respectfully,

Larry R. Helms Ph.D.

703-306-5879


SHEELA HUFF
PRIMARY EXAMINER